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09/701,908	01/22/2001	Christoph Heller	CU-2409 VE	1606

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Vangelis Economou
Ladas & Parry
Suite 1200
224 South Michigan Avenue
Chicago, IL 60604

EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1753

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7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,908

Applicant(s)

HELLER ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 4 of the specification describes the invention in part by referring to the claims by number. Please note that claim numbers are subject to change over the course of the examination and the examiner recommends the applicant remove any reference to claims by number from the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1, it is unclear how to interpret the limitation "being designed for taking samples by means of a micro-dispenser". In particular, claim 1 is drawn to an apparatus (i.e. a device) and apparatus claims should specify what the apparatus is and not what the apparatus does. It is unclear what structure is being explicitly defined by the above identified claim language. What would one possessing ordinary skill in the art reasonably construe as being a design for micro-dispensing? The examiner recommends the applicant modify the claim by defining the structure of the apparatus based on positive and explicit recitations of structure.

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5. Claims 8 and 9 are indefinite because the preambles of the claims are not drawn to clearly defined process steps. The examiner recommends the applicant modify the preamble of each claim to read --A method for performing electrophoresis--. Furthermore, the examiner recommends the applicant modify the body of claim 8 to read --providing the electrophoresis device of claim 1--.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1 and 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg et al (USP 6,086,825).

8. With respect to claim 1, Sundberg discloses an electrophoretic device that comprises a plurality of separation channels 78 that can be separately loaded with samples via a shared

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injection channel 76 where each area of the injection channel near the individual separation channels constitutes a sample channel area (fig. 7 and col. 9, lines 30-54). The injection channel intersects the separation channels (fig. 7). It would appear that said intersection would read on the term "crossing points" giving the claim language its broadest reasonable interpretation. In other words, it is not necessary for channel 78 to cross channel 76 because channel 76 clearly crosses channel 78. The ends of channel 76 have electrodes for providing electroosmotic (i.e. electrokinetic) flow of the fluid through the channel (col. 6, lines 47-58). Each of the intersections between the injection channel and the separation channel constitutes an application area giving the claim language its broadest reasonable interpretation.

9. With respect to claim 5, see fig. 3 and 7 in conjunction with col. 6, lines 59-64 and col. 9, lines 40-43).

10. With respect to claim 6, making the chip disposable is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

11. With respect to claim 7, having the device be "part" of an analyzer is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. With respect to the micro-dispenser, that is part of the unclaimed analyzer. However, a pipette 20 or pin 38 would appear to constitute a micro-dispenser of fluids.

12. With respect to claim 8 (those limitations not covered above), electrophoretic separation takes place along the separation channels 78 (col. 9, lines 30-43).

13. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg (USP 6,086,825) with evidence provided by Parce et al (USP 5,958,203).

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14. Sundberg specifies all the limitations of claim 9, but did not explicitly specify anything concerning electrically concentrating samples prior to the separation through the separation channels. Parce in an alternate sample injection device for a microfluidic device evidences that when electrokinetic means are utilized for sample transport (as Sundberg teaches utilizing), the ionic samples in question inherently become concentrated in parts because of the application of electrokinetic transport means (paragraph bridging col. 17 and 18). Because Sundberg relies on the analogous electrokinetic flow taught by Parce, then Sundberg would also inherently concentrate the sample prior to injection into the separation channels.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al (USP 5,958,203) in view of Sundberg (USP 6,086,825).

18. With respect to claim 1, Parce discloses an electrophoretic device that comprises a separation channel 110 that intersects at a crossing point an injection channel 112 (fig. 1, col. 6, lines 46-65). Parce further discloses electrodes for the purpose of generating an electric field in the injection channel (paragraph bridging col. 6 and 7). Parce does not explicitly disclose the presence of a plurality of separation channels intersecting with the injection channel. Sundberg teaches in an alternate electrophoretic device where an injection channel 76 can be utilized to supply sample to a plurality of separation channels intersecting with the injection channel (see discussion above with respect to this reference). Utilizing a plurality of separation channels for a given sample injection would allow one to perform many separations simultaneously thereby reducing analysis time. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Sundberg with the device of Parce in order to allow one to perform many separations simultaneously thereby reducing analysis time.

19. With respect to claims 2-4, see element 160 in figure 6A, which is a channel expansion that the applicant contends constitutes a molecular trap.

20. With respect to claim 5, see Parce, col. 1, lines 15-50 and col. 6, lines 46-50.

21. With respect to claim 6, making the chip disposable is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

22. With respect to claim 7, having the device be "part" of an analyzer is only the intended use of the apparatus and the intended use need not be given further due consideration in

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determining patentability. With respect to the micro-dispenser, that is part of the unclaimed analyzer.

23. With respect to claim 8 (those limitations not covered above), Sundberg teaches the use of micro-dispensers (20, 38) for introducing samples into an injection channel (col. 4, lines 65-67 and col. 5, lines 32-45) and Parce teaches performing electrophoresis on the samples in the separation channels (col. 6, lines 54-65).

24. With respect to claim 9, see paragraph bridging col. 17 and 18 of Parce.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guzman teaches structure very relevant to the instant invention, but Guzman does not qualify as prior art under 35 U.S.C. 102.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing

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of your papers. The fax number for regular communications is (703) 305-3599 and the fax number form after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj K. Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
August 4, 2003